



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0560; FRL-9954-63]

Bicyclopyrone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of bicyclopyrone in or on wheat and barley. Syngenta Crop Protection, LLC. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0560, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please

review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2015-0560 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0560, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 21, 2015 (80 FR 63731) (FRL-9935-29), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F8374) by Syngenta Crop Protection, LLC., P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR part 180.682 be amended by establishing tolerances for residues of the herbicide, bicyclopyrone: 4-hydroxy-3-{2-[(2-methoxyethoxy) methyl]-6-(trifluoromethyl)-3-pyridylcarbonyl} bicyclo oct-3-en-2-one, in or on the raw agricultural commodities: Barley, bran at 0.15 parts per million (ppm); barley, germ at 0.10 ppm; barley, grain, at 0.07 ppm; barley, hay at 0.3 ppm; barley, straw at 0.50 ppm; wheat, aspirated grain fractions at 0.50 ppm; wheat, bran at 0.15 ppm; wheat, forage at 0.50 ppm; wheat, germ at 0.10 ppm; wheat, grain, at 0.04 ppm; wheat, hay at 0.9 ppm; and wheat, straw at 0.50 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC., the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerances to wheat, forage at 0.40 ppm; wheat, hay at 0.80 ppm; wheat, bran at

0.07 ppm; grain, aspirated fractions at 0.30 ppm; and barley, straw at 0.40 ppm. EPA has increased the existing tolerances to cattle, meat byproducts at 2.0 ppm; goat, meat byproducts at 2.0 ppm; sheep, meat byproducts at 2.0 ppm; horse, meat byproducts; at 2.0 ppm; and hog, meat byproducts at 0.40 ppm. EPA has determined that tolerances are not needed to be established for barley, germ and wheat, germ. The reason for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for bicyclopyrone

including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with bicyclopyrone follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The effects of bicyclopyrone are indicative of inhibition of 4-hydroxyphenylpyruvate dioxygenase (HPPD). Plasma tyrosine levels were consistently elevated in rats, rabbits, and dogs (levels in mice were not tested). Consistent with these elevated tyrosine levels, ocular effects (corneal opacity, keratitis) were observed for subchronic and chronic durations through the oral and dermal routes in rats, which was the most sensitive species tested (minor instances in dogs). There were also increased incidences of thyroid follicular hyperplasia and a chronic progressive nephropathy.

While minor instances of ocular effects were observed in dogs, different toxicological effects were generally observed. For subchronic oral exposure, clinical signs (moderate hypoactivity, slightly unsteady gait, increased heart rate, regurgitation, and vomiting) were observed, and clinical pathological indicators of toxicity occurred in the eye and the thymus. Following chronic exposure, there was a dose-dependent increase in chromatolysis and swelling of selected neurons in the dorsal root ganglia, and degeneration of nerve fibers in the spinal nerve roots in both sexes. In one female dog at the high dose, corneal opacity and light sensitivity were observed.

Across the database, there were decreased absolute body weights (the only finding in mice for any duration) and food consumption. There were no signs of immunotoxicity or neurotoxicity in rodents.

Bicyclopyrone treatment resulted in developmental toxicity in both rats and rabbits, and there was an increased quantitative fetal susceptibility in both species tested. In rats, maternal toxicity was not observed up to 1,000 milligram/kilogram/day (mg/kg/day). Fetal effects occurred at all doses (≥ 100 mg/kg/day), and manifested as skeletal variations (increased incidences of full or rudimentary supernumerary ribs, pelvic girdle malpositioned caudal, costal cartilage 11 long). In New Zealand White rabbits, maternal effects consisted of mortality/moribundity in conjunction with minimal food consumption at 200 mg/kg/day. Fetal effects once again occurred at all doses tested (≥ 10 mg/kg/day). The sole fetal effect at the lowest dose tested was the appearance of the 27th presacral vertebrae. There were two studies in Himalayan rabbits. In both studies, maternal effects consisted of macroscopic findings in the stomach wall and an increased incidence of post-implantation loss at the 250 mg/kg/day dose level. In the first study, fetal effects occurred starting at 50 mg/kg/day and consisted of skeletal variations (increased incidence of the 27th prepelvic vertebra and malpositioned pelvic girdle). In the second study, the increased quantitative fetal susceptibility was not observed due to a change in the dose selection. Fetal effects occurred at 250 mg/kg/day and consisted of external, visceral, and skeletal abnormalities, and visceral variations, skeletal, bone and cartilage variations. In total, the effects in these studies are consistent with effects of other chemicals in this class.

In the two-generation reproductive study in rats, ocular toxicity occurred in parents and offspring and there was no increased offspring susceptibility of any kind. Reproductive effects included changes in sperm parameters, and a decrease of precoital interval.

To determine the mechanism for the thyroid hyperplasia observed in the chronic/carcinogenicity study in rats, two mode-of-action studies were performed. In the *in vitro* study, bicyclopyrone was negative for thyroid peroxidase inhibition. The results from the *in vivo* study suggested that the observed thyroid hyperplasia was the result of increased metabolism of thyroid hormones indicated by: 1) decreased plasma T3 and T4 levels, 2) increased thyroid follicular cell hypertrophy, 3) increased liver weights associated, and 4) increased hepatocellular centrilobular hypertrophy and increased hepatic uridine diphosphate glucuronyl transferase (UDPGT) activities. Bicyclopyrone is categorized as having low acute lethality via all routes of administration. Bicyclopyrone produces minimal eye irritation and mild acute inhalation toxicity.

Two adequate carcinogenicity studies were submitted. One study conducted on rats showed the presence of rare ocular tumors in male rats only. The corneal tumors observed in male rats are (1) treatment related, (2) found at doses that were considered to be adequate and not excessive for assessing carcinogenicity, (3) there are no concerns for mutagenicity or genotoxicity, and (4) are supported by structure-activity relationship (SAR) data for another HPPD inhibitor, tembotrione. Another study conducted on mice showed lung tumors, which are not considered treatment related. Because the tumors are found only in one species and only in males, consistent with the Agency guidelines for

carcinogen risk assessment, the Agency has classified bicyclopyrone as “suggestive evidence of cancer” and has determined that quantification of bicyclopyrone’s carcinogenic potential is not required. A non-linear approach (i.e., reference dose (RfD)) will adequately protect for all chronic toxicity, including carcinogenicity that could result from exposure to bicyclopyrone. Using EPA’s non-linear approach, the 1000X combined uncertainty factor used to calculate the chronic RfD/chronic population-adjusted dose for the chronic dietary assessment, generates a dose which is 10,000-fold lower than the dose at which the ocular tumors were not observed and is thus protective of their potential formation.

Specific information on the studies received and the nature of the adverse effects caused by bicyclopyrone as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document titled “Bicyclopyrone: Human Health Risk Assessment for the Section 3 Registration Action on Cereals (Wheat and Barley)” at pp. 29-34 in docket ID number EPA-HQ-OPP-2015-0560.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in

conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a RfD - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for bicyclopyrone used for human risk assessment is discussed in Unit III. B of the final rule published in the **Federal Register** of April 23, 2015 (80 FR 22648) (FRL-9926-66).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to bicyclopyrone, EPA considered exposure under the petitioned-for tolerances as well as all existing bicyclopyrone tolerances in 40 CFR 180.682. EPA assessed dietary exposures from bicyclopyrone in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for bicyclopyrone. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003-2008 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). The acute dietary analysis was conducted for bicyclopyrone assuming tolerance level residues, default processing factors, and 100% crop treatment (PCT) information.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003-2008 CSFII. The chronic dietary exposure assessment was conducted for bicyclopyrone assuming average field trial residues for crops, average empirical processing factors, anticipated residues for livestock commodities, and PCT estimates for some commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has determined that a separate cancer exposure assessment does not need to be conducted.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data calls as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition A: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition B: The exposure estimate does not underestimate exposure for any significant subpopulation group.

- Condition C: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows: The chronic analysis incorporated the following PCT estimates: Field corn, 40% and sweet/popcorn, 35%. The PCT for livestock commodities is based on the PCT estimate value for the livestock feed item used in the dietary burden with the highest PCT (field corn, 40%).

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6-7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency estimated the PCT for new uses as follows: The chronic analysis incorporated the following PCT estimates: Barley, 5% and wheat, 1%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition A, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions B and C, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which bicyclopyrone may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for bicyclopyrone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of bicyclopyrone. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

The Surface Water Concentration Calculator (SWCC) computer model was used to generate surface water Estimated Drinking Water Concentrations (EDWCs), while the Pesticide Root Zone Model for Groundwater (PRZM-GW) and the Screening Concentration in Ground Water (SCI-GROW) models were used to generate groundwater EDWCs. The maximum acute, chronic, and cancer surface water EDWCs associated with bicyclopyrone use on wheat and barley were 3.43, 1.02, and 0.46 parts per billion (ppb), respectively. For groundwater sources of drinking water, the maximum acute, chronic and cancer EDWCs of bicyclopyrone in shallow groundwater from PRZM-GW were 4.82, 4.2, and 2.1 ppb, respectively. EDWCs of 4.82 ppb and 4.2 ppb were used in the acute and chronic analyses, respectively.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Bicyclopyrone is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

There are marked differences among species in the ocular toxicity associated with bicyclopyrone's mechanism of toxicity, the inhibition of HPPD. Ocular effects following treatment with HPPD inhibitor herbicides are seen in the rat but not in the mouse.

Monkeys also seem to be recalcitrant to the ocular toxicity induced by HPPD inhibition. One explanation for this species-specific response in ocular opacity may be related to species differences in the clearance of tyrosine. A metabolic pathway exists to remove tyrosine from the blood that involves the liver enzyme tyrosine aminotransferase (TAT). In contrast to rats where ocular toxicity is observed following exposure to HPPD-inhibiting herbicides, mice and humans are unlikely to achieve the levels of plasma tyrosine necessary to produce ocular opacities because the activity of TAT in these species is much greater compared to rats.

HPPD inhibitors (e.g., nitisinone) are used as an effective therapeutic agent to treat patients suffering from rare genetic diseases of tyrosine catabolism. Treatment starts in childhood but is often sustained throughout patient's lifetime. The human experience indicates that a therapeutic dose (1 mg/kg/day dose) of nitisinone has an excellent safety record in infants, children, and adults and that serious adverse health outcomes have not been observed in a population followed for approximately a decade. Rarely, ocular effects are seen in patients with high plasma tyrosine levels; however, these effects are transient and can be readily reversed upon adherence to a restricted protein diet. This observation indicates that an HPPD inhibitor in and of itself cannot easily overwhelm the tyrosine-clearance mechanism in humans.

Therefore, exposures to environmental residues of HPPD-inhibiting herbicides are unlikely to result in the high blood levels of tyrosine and ocular toxicity in humans due to an efficient metabolic process to handle excess tyrosine. The EPA continues to study the complex relationships between elevated tyrosine levels and biological effects in various species. In the future, assessments of HPPD-inhibiting herbicides may consider more

appropriate models and cross species extrapolation methods. Therefore, EPA has not conducted cumulative risk assessment with other HPPD inhibitors.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. The FQPA SF is retained at 10X for all exposure scenarios based on use of a LOAEL for the points of departure. The toxicology database for bicyclopyrone is adequate for characterizing toxicity and quantification of risk for food and non-food uses; however, a LOAEL from the New Zealand white rabbit developmental and chronic/carcinogenicity rat toxicity studies has been used as the POD for several scenarios.

There is no evidence of neurotoxicity in either of the neurotoxicity screening batteries, but there are effects in the chronic dog study. The level of concern is low, however, since the study and POD chosen for the chronic dietary exposure scenario is protective of these effects. There is evidence of increased quantitative fetal susceptibility following *in utero* exposure in both rats and rabbits; however, these effects are well

characterized and the selected endpoints are protective of the observed fetal effects.

Lastly, there are no residual uncertainties in the exposure database.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to bicyclopyrone will occupy 4.6% of the aPAD for females 13-49 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to bicyclopyrone from food and water will utilize 90% of the cPAD for children <1 years old the population group receiving the greatest exposure. There are no residential uses for bicyclopyrone.

3. *Short-term risk.* A short-term adverse effect was identified; however, bicyclopyrone is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no

further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for bicyclopyrone.

4. *Intermediate-term risk.* An intermediate-term adverse effect was identified; however, bicyclopyrone is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for bicyclopyrone.

5. *Aggregate cancer risk for U.S. population.* Because the Agency has determined that the chronic RfD will be protective of any potential cancer risk and there is not a chronic risks do not exceed the Agency's level of concern, EPA concludes that there is not a concern for cancer risk from exposure to bicyclopyrone.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to bicyclopyrone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology liquid chromatography-mass spectroscopy/mass spectroscopy (LC-MS/MS) methods for tolerance enforcement have been developed and independently validated. For all matrices and analytes, the level of

quantification (LOQ), defined as the lowest spiking level where acceptable precision and accuracy data were obtained, was determined to be 0.01 ppm for each of the common moieties, SYN503780 and CSCD686480, for a combined LOQ of 0.02 ppm is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for bicyclopyrone.

C. Revisions to Petitioned-For Tolerances

The requested tolerance levels for some wheat and barley raw agricultural commodities (RAC) differ slightly from those being set by the EPA. Although both the petitioner and EPA have used the Organization for Economic Cooperation and

Development (OECD) calculation procedures to determine tolerance levels, EPA determined that some of the field residue trials were not independent, thus resulting in different inputs. Using the highest average RAC residues and average processing factors, EPA calculated tolerance levels for processed commodities that were generally lower than those requested and determined that the requested tolerances for residues in/on wheat and barley germ are not necessary as the expected residue levels are covered by the RAC tolerance levels.

Consistent with 40 CFR 180.6, EPA is amending existing livestock commodity tolerances as necessary. As a result of increased dietary burdens resulting from the use on wheat and barley commodities, the existing tolerances of 1.5 ppm for residues in/on the meat byproducts of cattle, goats, horses, and sheep are increased to 2.0 ppm; and the existing tolerance of 0.15 ppm for residues in/on for hog meat byproducts is increased to 0.40 ppm.

In addition, EPA changed the commodity terminology for aspirated grain fractions to grain, aspirated fractions in order to conform to terms used in the Agency's Food and Feed Commodity Vocabulary and amended the tolerance value for barley, hay from 0.3 ppm to 0.30 ppm to conform with the Agency policy to carry tolerance levels out two significant figures.

V. Conclusion

Therefore, tolerances are established for residues of the herbicide bicyclopyrone in or on barley, bran at 0.15 ppm; barley, grain, at 0.07 ppm; barley, hay at 0.30 ppm; barley, straw at 0.40 ppm; cattle, meat byproducts at 2.0 ppm; goat, meat byproducts at 2.0 ppm; grain, aspirated fractions at 0.30 ppm; hog, meat byproducts at 0.40 ppm; horse,

meat byproducts at 2.0 ppm; sheep, meat byproducts at 2.0 ppm; wheat, bran at 0.07 ppm; wheat, forage at 0.40 ppm; wheat, grain, at 0.04 ppm; wheat, hay at 0.80 ppm; and wheat, straw at 0.50 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of

power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 3, 2016.

Michael Goodis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.682, revise the table in paragraph (a)(1) to read as follows:

§ 180.682 Bicyclopyrone; tolerances for residues.

(a) * * * (1) * * *

Commodity	Parts per million
Barley, bran	0.15
Barley, grain	0.07
Barley, hay	0.30
Barley, straw	0.40
Cattle, meat byproducts	2.0
Corn, field, forage	0.30
Corn, field, grain	0.02
Corn, field, stover	0.40
Corn, pop, grain	0.02
Corn, pop, stover	0.40
Corn, sweet, forage	0.40
Corn, sweet, kernel plus cob with husks removed	0.03
Corn, sweet, stover	0.70
Goat, meat byproducts	2.0
Grain, aspirated fractions	0.30
Hog, meat byproducts	0.40
Horse, meat byproducts	2.0
Sheep, meat byproducts	2.0
Sugarcane, cane ¹	0.02
Wheat, bran	0.07
Wheat, forage	0.40
Wheat, grain	0.04
Wheat, hay	0.80
Wheat, straw	0.50

¹ There are no U.S. Registration on Sugarcane as of March 13, 2015.

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